

The Use of Herbal Preparation In The Management of Insomnia: A Review Article

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Abstract- *Insomnia, a prevalent sleep disorder, poses significant health risks and impairs daily functioning. In this study, a herbal buccal tablet was formulated utilizing natural ingredients known for their sedative and calming properties. The formulation consisted of nutmeg, magnesium stearate, lavender oil, tragacanth gum, starch, lactose, ashwagandha, and cinnamon. The tablets were prepared using a direct compression method and evaluated for various parameters including weight variation, hardness, friability, disintegration time, and drug release profile. The inclusion of nutmeg, ashwagandha, and cinnamon aimed to harness their sedative effects, while lavender oil provided a soothing aroma known for its calming properties. Tragacanth gum and starch served as binding agents, ensuring the integrity of the tablet structure, while lactose acted as a filler. The formulated herbal buccal tablet demonstrated promising characteristics, suggesting its potential as a novel approach for managing insomnia. Further pharmacokinetic and clinical studies are warranted to ascertain its efficacy and safety for insomnia management.*

Keywords- Insomnia, Buccal tablet, Lavender oil, Anxiety , Nutmeg, stress

I. INTRODUCTION

Insomnia is technically defined as difficulty falling asleep, staying asleep, or falling asleep uncontrollably, causing disability or discomfort during the day, despite adequate opportunities and periods of sleep occurring at least three times a week for at least a month. Plants have been used by all cultures throughout history.[1] Insomnia is a sleep disorder that can affect a person's life both physically and mentally.[2] Sleep disorders occur when sleep quality causes you to function poorly or sleep too much. Over the past four decades, Prescription drugs (benzodiazepines or non-benzodiazepines) have been commonly used to treat sleep problems in adults and children. However, side effects associated with chronic use (addiction, increased abuse potential, withdrawal symptoms) are concerning.[3] Disruption of neurotransmitters or endogenous sleep control is associated with insomnia. Neurotransmitters involved in the regulation of sleep and circadian rhythms include gamma-aminobutyric acid (GABA), serotonin, melatonin, histamine, prostaglandins,

and hypocretin or orexin.[4] Life is full of unexpected events that cause People to experience sleepless nights or short-term symptoms of insomnia from time to time ; However, when these symptoms persist over a long period of time, they can have a significant impact on individual functioning and quality of life (QoL).[5] Treatment of insomnia includes medication and intervention ; But patients also use complementary and alternative medicine (CAM) to help them sleep. Over-the-counter (OTC) herbal medicines are used to relieve insomnia symptoms, and there has been an increase in CAM use in recent years. 8 Reasons for using CAM include health benefits. And/or take a comprehensive approach to life[6]

Nutmeg powder and lavender oil (helps to reduce insomnia) are collected from the local market. Magnesium stearate, gum tragacanth (as a mucoadhesive), starch (as a binder), and lactose (as a diluent) these all ingredients were collected from college laboratory

II. HERBAL TREATMENT

1. Nutmeg powder



Fig 1. Nutmeg powder

Myristic, commonly known as Nutmeg, belongs to the Myristicaceae family and is a medium-sized evergreen tree.[7] Myristica seeds are also used for heartburn, mouth ulcers and insomnia. Malabaricon C extracted from Myristica fragrans has been shown to have inhibitory activity against various types of anaerobic and aerobic microorganisms.[8] The antibacterial effect of the essential oil obtained from the fragrant seeds of Myristica was tested in a study on 25

bacterial species and was found to have a positive effect against bad bacteria and bad bacteria.[9]Experiments have shown that the dry extract of nutmeg seeds has a strong antifungal and antibacterial effect. The dried bark of *Myristica* contains two compounds, both of which exhibit potent antifungal and antibacterial [10]

2. Lavender oil



Fig 2. Lavender oil

Lavender oil has an anti-inflammatory effect due to its high concentration of linalool and linalyl acetate, which inhibit inflammatory cytokines. Lavender oil, obtained from the lavender plant (*Lavandula angustifolia*), is known for its aromatic and therapeutic properties, including anti-inflammatory effects. Lavender oil exerts its anti-inflammatory effects through various mechanisms.[11]Stress can be aggravating, and lavender oil For relaxation and stress reduction can directly help reduce inflammation. Several primary studies have focused on the anti-inflammatory effects of lavender oil and its components These studies have shown efficient results in reducing inflammation such as paw edema caused by carrageenan by suppressing symptoms in various animal models. Clinical Studies have compared to previous studies in the field of anti-inflammatory lavender oil There are limitations. However, some studies have shown its potential[12]

Pain relief: Lavender oil massage or aromatherapy can provide relief from Conditions characterized by pain and inflammation, such as musculoskeletal disorders.

Skin Health: Lavender oil can be widely used to soothe skin irritations, minor burns, and insect bites

Stress Relief: Reducing stress with lavender oil can directly help control inflammation in stress-related conditions.

Respiratory Health: Inhaling lavender essential oil soothes breathing and may provide anti-inflammatory properties [13]

3.Valerian



Fig 3. Valerian flower

Valerian, a herbal product consisting of the root of *Valeriana officinalis*, has been used in the treatment of insomnia since ancient Greek and Roman times.[14] It appears to create a calming effect by interacting with GABAergic neurotransmission.[15]While some studies have shown valerian to be effective in treating patients with insomnia, other studies have not. Interpretation of available clinical data is complicated by the small sample size, the use of different amounts and sources of valerian, the variability of measured results, and the high cost of extracting them. Overall, the indications for valerian use in the treatment of insomnia remain unclear and its use is not recommended in these patients.[16]Although the key chemical responsible for In valerian remains unclear, it has been suggested that Valepotriates, valerenic acid, and their derivatives contribute to the astringent effects of . Pharmacological effects of valerianfunction of GABAergic Receptors.Valerian has been reported to be an herbal supplement that has positive, although not negative, side effects. A large amoutherapeutic nt of valerian Needs to be ingested to produce a significant effect; Report of intentional overdose of 20 times the recommended dose showed that the patient experienced only mild problems such as chest tightness and abdominal pain.[17]

In the literature that contradict the idea of the statement: Valeria Has no side effects and there are concerns about its effectiveness, but hepatotoxicity of valerian has been reported. Research on valerian and insomnia has been fruitful. There are Vague answers about the capabilities of this

4.Kava-kava



Fig 4. Kava- kava

The kava kava tree (*Piper methysticum*) is native to the Pacific Islands, where it is the sole source of the family beverage. Kava-kava is believed to have anxiolytic and sedative properties,²⁹ but there is no research to suggest this is not the case. Not only researched insomnia, but also solved the problem of insomnia.^[18] Patients suffering from insomnia were administered 120 mg of kava-kava Times a day for 6 weeks. The results showed statistically significant improvements in sleep latency, duration, and alertness. In contrast, in the other Studies, 121 participants were given kava-kava three times a day for 28 days; No reduction in insomnia symptoms compared to placebo^[19] However, this study did not use diagnostic criteria to determine whether Participants had insomnia, and therefore the overall study was underpowered. Serious concerns have been raised about the safety of using kava-kava supplements, including dermatological reactions, neurological problems, and liver damage.^[20] The study found that the difference between baseline and end of treatment in the kava group was Points for sleep ability (0.6 for Kava and 0.36 for placebo; p-value 0.007) and Points for the post-sleep rebound effect (0.80 for kava). And 0.64). p-value for space 0.018); Further studies are needed to support this research and confirm the effectiveness of kava in treating chronic insomnia.

PATHOPHYSIOLOGY OF INSOMNIA

The various factors that commonly cause insomnia are psychological, physical, biological, environmental factors and their interactions. Insomnia is often thought to be a disorder associated with overstimulation^[21] Patients suffering from insomnia may experience physiological overstimulation in the peripheral and central nervous systems. Overarousal can also be characterized as an emotional and cognitive process; Some theories suggest that hyperarousal and cognitive processes during sleep may lead to excessive and restorative

sleep.^[22] Overarousal can be identified by EEG measurements, mood swings, increased cortisol, or self-report. Overall, the evidence presented above suggests that is heritable and plays an important role in the pathophysiology of insomnia. Approximately of the genes found to be linked to insomnia are genes related to sleep-wake, wakefulness, and brain activity. Unwanted interaction of these genes is responsible, at least to a limited extent, for the differences discovered in insomnia symptoms and consequences. Future research and comprehensive evaluation of the health and sleep history of individuals with chronic insomnia may further improve our understanding of the genetics of insomnia.

EPIDEMIOLOGICAL OF INSOMNIA

Population-based estimates indicate that one-third of adults report symptoms of insomnia, 10-15% have daytime sleepiness, and 6-10% have symptoms that meet criteria for insomnia. Insomnia is the most common sleep disorder in primary care, with approximately 10-20% of people suffering from severe insomnia;^[23]

For example, 40-50% of people with insomnia also have an additional mental health problem. Risk factors include depression, female gender, older age, poor social status, and medical and psychological conditions. Disorder, marital status (higher risk in divorced/separated and Married or never married) and gender (higher risk associated with activity relative to other insomnia symptoms in 04, with a higher prevalence and higher levels in young adults causes) Preventing disability sleepiness and fatigue during the day Because different people have different sleep needs, insomnia is determined by the quality of our sleep. Even if we spend eight hours a night in bed, we can experience insomnia if we feel sleepy and tired. Day. Short-term insomnia occurs during times of stress or while on a plane (03 African American and Caucasian).^[24]

ETIOLOGY OF INSOMNIA

Many patients report having been marginal light sleepers before developing insomnia ^[25]

Sleep disorders often occur during life changes or stress and may be indicative of normal short-term sleep disturbance. However, secondary conditions such as sleep anxiety and sleep disorders can increase insomnia and cause it to persist as a chronic problem when sleep becomes the focus. Due to stress, insomniacs may be more aroused than normal sleepers; for example, they have higher cortisol and ACTH levels and also have difficulty suppressing their urges before bed.^[26,27,28] In medical practice, insomnia often occurs

secondary to other problems, especially excruciating physical pain, stress, anxiety, and depression. It also occurs with the abuse of alcohol, caffeine, and other prescription or prescription drugs. In approximately 15% of insomnia cases, there is no known cause.[29]

MANAGEMENT

Sleep management should reveal priorities and focus on some underlying causes and comorbid conditions. For example, opioid therapy for pain may facilitate sleep due to the side effects of opioids, but may have adverse effects on breathing in patients with poor cardiac function. On the other hand, gabapentin treatment can help improve sleep and can be used effectively in many patients with heart failure. Research shows use. Goals of insomnia treatment include improving the quality and quantity of sleep, reducing discomfort and anxiety associated with insufficient sleep, and improving daytime functioning. One way to treat insomnia is with a combination of psychotherapy and medication. “The causes of insomnia and possible comorbidities in all patients should be determined as part of the strategic management plan.[30,31]

MOLECULAR MECHANISM OF SLEEP AND INSOMNIA

Various sleep regulatory factors play a role in regulating sleep and circadian rhythms. Although people consider this to be unnecessary [32] endogenous factors are reported to be mainly classified into sleep inducers/depressants (such as γ -aminobutyric acid [GABA], prostaglandin D2, serotonin, adenosine, and melatonin) and sleep inhibitors/stimulants (such as orexins, such as catecholamines and histamine). Few molecular studies have been conducted on insomnia and a few molecules are the most important (e.g. cortisol and GABA). Results across studies have been mixed, and a consistent molecular type (that triggers wakefulness and sleep) has not emerged. Despite conflicting evidence, the findings have largely been explained using the hyperarousal model. For example, increased [33] and decreased GABA levels in the occipital cortex of insomniacs have been found to be consistent with the hypothetical hypothesis of insomnia. However, the molecules that regulate sleep are unprogrammed and many of their effects depend on the brain state, that is, situation dependent. The above parameters exclude the possibility that all cases of insomnia can be explained by changes in any molecular structure (e.g. associated with overstimulation). A more detailed explanation states that chronic insomnia results from disruption of the Alternative parts of the sleep cycle that regulate sleep and stimulate brain activity [34]

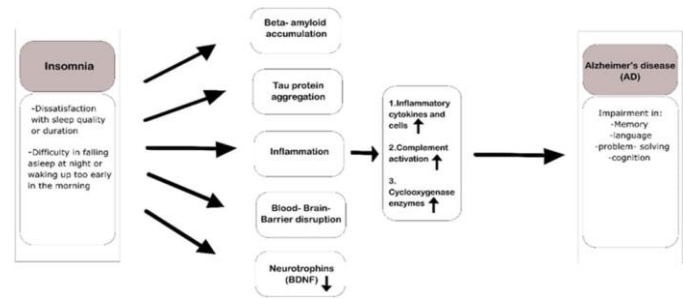


Fig no:5- Molecular mechanism of sleep

DIAGNOSIS

Insomnia is a sleep disorder in which a person cannot complete Hours of sleep for various reasons that vary from person to person[35,36] The most common symptoms that people actually experience are inattention, depression, working less, social behavior, aggression, mood swings and fatigue, etc. The rating is evaluated according to sleep problems, sleep disruption, or early morning awakening [37]

Diagnostic test for insomnia –

To Sleep-graph is a patient's sleep and wake time and related data; usually over a period of several weeks. It was developed by human and sessionphy- To record sleep duration This is an important tool in diagnosing insomnia with the help of a diary, which helps treat patients better.[38,39]

Laboratory-based polysomnography (PSG)- It is used to diagnose obstructive sleep apnea syndrome (OSAS). It can be used to diagnose a variety of sleep disorder Such as periodontal disease, chronic insomnia, narcoleps and REM sleep disorder [40]

Athens Insomnia scale (AIS)

The commonly used is used to measure sleep It has 8 parameters, where parameters 1 to 5 are related to night sleep, and parameters 6, 7 and 8 are related to inactivity during the day. ASI parameter variables include sleep development, night awakenings, last awakenings, total sleep time, sleep duration, daytime well-being, daytime functional capacity, and daytime sleepiness [41,42]

Multiple Sclerosis Sleep Test (MSLT)-

It is a diagnostic tool for insomnia, defined as the time from the onset of daytime sleepiness to the first signs of sleepiness, called delayed sleep onset. It is used to distinguish excessive bodyfatigue and even daytime sleepiness. The focus is on investigating sleep patterns related to REM sleep and

other brain processes. It is also used to identify and differentiate Different sleep disorders [43]

III. CONCLUSION

Insomnia or insomnia is becoming popular in today's society Because many people get sick for any reason and it is very difficult to recover insomnia not only affects daily life, but also causes poor mood and health if the disease persists. However, by using simple insomnia methods that make it easier to fall asleep with healthy herbs and fall asleep quickly, we can completely eliminate this disease and restore good sleep. It looks average but its value is .Chronic insomnia is associated with an increased risk of chronic diseases, and therefore underlying causes need to be identified and treated. Treatment of insomnia includes medication, cognitive behavioral therapy and physical therapy. The main goals of treatment are to improve sleep and mood, improve daily functioning, and reduce anxiety.

REFERENCES

- [1] Abourashed EA.khan IA, Abourashed EA, editors Leung's Encyclopedia of common natural ingredients use in food ,drug and cosmetics.
- [2] Mariani D, Muzasti RA, Thamrin A. The Relationship Between Quality of Sleep and Quality of Life of Patients in Medan, Indonesia. *Open Access Maced J Med Sci.* 2019;7(11):1794–7. Doi:10.3889/oamjms.2019.353. [PMC free article] [PubMed] [Google Scholar]
- [3] 4. Glass J, Lanctôt KL, Herrmann N, Sproule BA, Busto UE (2005) Sedative hypnotics in older people with insomnia: meta-analysis of risks and benefits *BMJ* 331: 1169.
- [4] Levenson JC, Kay DB, Buysse DJ. The pathophysiology of insomnia. *Chest.* 2015;147(4):1179–92. Doi:10.1378/chest.14-1617. [PMC free article] [PubMed] [Google Scholar]
- [5] Doghramji K. The evaluation and management of insomnia. *Clin Chest Med* 2010;31:327–339
- [6] Jefferson J. Herbal psychopharmacology: Show me the data. *Psychopharmacol Rev* 2009;44:25–32.
- [7] Anonymous. *Wealth of India: Raw materials*. Vol. VI. Council of Scientific and Industrial Research, New Delhi; 1962. P. 474-6.
- [8] Shinohara C, Mori S, Ando T, Tsuji T. Arg-gingipain inhibition and anti-bacterial activity selective for *Porphyromonas gingivalis* by malabaricone C. *Biosci Biotechnol Biochem* 1999;63:1475-7.
- [9] Dorman HJ, Deans SG. Antimicrobial agents from plants: antibacterial activity of volatile plant oils. *J Appl Microbiol* 2000;88:308-16
- [10] Orabi KY, Mossa JS, el-Ferally FS. Isolation and characterization of two antimicrobial agents from mace (*Myristica fragrans*). *J Nat Prod* 1991;54:856-9.
- [11] G. L. da Silva et al., “Antioxidant, analgesic and anti-inflammatory effects of lavender essential oil,” *An. Acad. Bras. Cienc.*, vol. 87, no. 2, pp. 1397–1408, 2015, doi: 10.1590/0001-3765201520150056
- [12] The United State Pharmacopeia (USP) 30, NF28, 2010, USA: The United State Pharmacopia Convention Inc.
- [13] N. Aboutaleb, H. Jamali, M. Abolhasani, and H. Pazoki Toroudi, “Lavender oil (*Lavandula angustifolia*) Attenuates renal ischemia/reperfusion injury in rats through suppression of inflammation, oxidative stress and Apoptosis,” *Biomed. Pharmacother.*, vol. 110, no. November 2018, pp. 9–19, 2019, doi: 10.1016/j.biopha.2018.11.045.
- [14] National Institutes of Health Valerian: fact sheet for health professionals. Mar 15, 2013. Available at: <https://ods.od.nih.gov/fact-sheets/Valerian-HealthProfessional/>. Accessed September 11, 2015.
- [15] Santos MS, Ferreira F, Cunha AP, et al. An aqueous extract of valerian influences the transport of GABA in synaptosomes. *Planta Medica.* 1994;60:278–279. [PubMed] [Google Scholar]
- [16] 16) Stevinson C, Ernst E. Valerian for insomnia: a systematic review of randomized clinical trials. *Sleep Med.* 2000;1:91–99. [PubMed] [Google Scholar]
- [17] Yuan CS, Mehendale S, Xiao Y, et al. The gamma-aminobutyric acidergic Effects of valerian and valerenic acid on rat brainstem neuronal activity. *Anesth Analg* 2004;98:353–358.
- [18] Cairney S, Maruff P, Clough AR, et al. Saccade and cognitive impairment Associated with kava intoxication. *Hum Psychopharm Clin* 2003;18:525–533.
- [19] Jacobs BP, Bent S, Tice JA, et al. An internet-based randomized, placebo-controlled trial of kava and valerian for anxiety and insomnia. *Medicine* 2005;84:197–207.
- [20] Stevinson C, Huntley A, Ernst E. A systematic review of the safety of kava Extract in the treatment of anxiety. *Drug Saf* 2002;25:251–261
- [21] D. Riemann, K. Spiegelhalder, B. Feige et al., “The hyperarousal model of insomnia: a review of the concept and its evidence,” *Sleep Medicine Reviews*, vol. 14, no. 1, pp. 19–31, 2010. View at: Publisher Site | Google Scholar
- [22] C. A. Espie, “Insomnia: conceptual issues in the development, persistence, and treatment of sleep disorder in adults,” *Annual Review of Psychology*, vol. 53, no. 1, pp. 215–243, 2002. View at: Publisher Site | Google Scholar
- [23] American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders* 5th ed. Arlington, VA: American Psychiatric Association; 2013.

- [24] Ohayon MM. Epidemiology of insomnia: What we know and what we still need to learn. *Sleep Med Rev* 2002; 6(2): 97-111
- [25] Reite M, Buysse D, Reynolds C, Mendelson WB, et al. The use of polysomnography in the evaluation of insomnia. *Sleep* 1995; 18(1): 58-70.
- [26] Morin CM, Espie CA. *Insomnia: a clinical guide to assessment and treatment*. New York: Kluwer Academic/Plenum Publishers; 2003.
- [27] Espie CA. Insomnia: conceptual issues in the development, persistence and treatment of sleep disorder in adults. *Annu Rev Psychol* 2002; 53: 215-43.
- [28] Perlis ML, Pigeon W, Smith MT. Etiology and pathophysiology of insomnia. In: Kryger MH, Roth T, Dement WC (ed.). *The principles and practice of sleep medicine* 4th ed. Philadelphia: W.B. Saunders; 2005.
- [29] Harrison P, Cowen P, Burns T, Fazel M. *Shorter Oxford textbook of psychiatry* 7th ed. Oxford: Oxford University Press; 2017.
- [30] Kriesen AR. Continuing education for pharmacists. *General Insomnia Disorder in Adults and Treatment Guidelines*. 2017. Volume XXXV, No. 9.
- [31] M alan L, Dlamini N. Clinical practice guidelines for insomnia disorder. *South African Family* 2018 Vol 85 No 2S Afr Pharm J 38REVIEWPractice. 2017;59(3):45-51
- [32] P. T. Morgan, E. F. Pace-Schott, G. F. Mason et al., "Cortical GABA levels in primary insomnia," *Sleep*, vol. 35, no. 6, pp. 807–814, 2012. View at: [Publisher Site](#) | [Google Scholar](#)
- [33] J. M. Dzierzewski and E. M. O'Brien, "Tackling sleeplessness: psychological treatment options for insomnia in older adults," *Nature and Science of Sleep*, vol. 2, pp. 47–61, 2010. View at: [Publisher Site](#) | [Google Scholar](#)
- [34] H. P. Roffwarg, "Association of sleep disorders centers: diagnostic classification of sleep and arousal disorders," *Sleep*, vol. 2, pp. 1–137, 1979. View at: [Google Scholar](#)
- [35] K. Chigome, S. Nhira, and J. C. Meyer, "An overview of Insomnia and its management," *SA Pharmaceutical Journal*, Vol. 85, no. 2, pp. 32–38, 2018.
- [36] Y. Lian, J. Xiao, Y. Liu et al., "Associations between insomnia, Sleep duration and poor work ability," *Journal of Psychoso-Matic Research*, vol. 78, no. 1, pp. 45–51, 2015.
- [37] American Academy of Sleep Medicine, International Classification of Sleep Disorders, American Academy of Sleep Medicine, 3rd edition, 2014.
- [38] D. Riemann, "European guideline for the diagnosis and treatment of insomnia," *Journal of Sleep Research*, vol. 26, no. 6, pp. 675–700, 2017.
- [39] L. P. Michael and J. Q. Carla, "The cognitive behavioural treatment of insomnia: a session-by-session guide," *Springer Science & Business Media*, vol. 33, no. 50, 2005.
- [40] W. C. Orr, "Utilization of polysomnography in the assessment of sleep disorders," *The Medical Clinics of North America*, vol. 69, no. 6, pp. 1153–1167, 1985.
- [41] C. R. Soldatos, D. G. Dikeos, and T. J. Paparrigopoulos, "Athens Insomnia Scale: validation of an instrument based on ICD-10 criteria," *Journal of Psychosomatic Research*, vol. 48, No. 6, pp. 555–560, 2000.
- [42] C. R. Soldatos, D. G. Dikeos, and T. J. Paparrigopoulos, "The Diagnostic validity of the Athens Insomnia Scale," *Journal of Psychosomatic Research*, vol. 55, no. 3, pp. 263–267, 2003.
- [43] G. S. Richardson, M. A. Carskadon, W. Flagg, J. van den Hoed, W. C. Dement, and M. M. Mitler, "Excessive daytime Sleepiness in man: multiple sleep latency measurement in narcoleptic and control subjects," *Electroencephalography and Clinical Neurophysiology*, vol. 45, no. 5, pp. 621–627, 1978.